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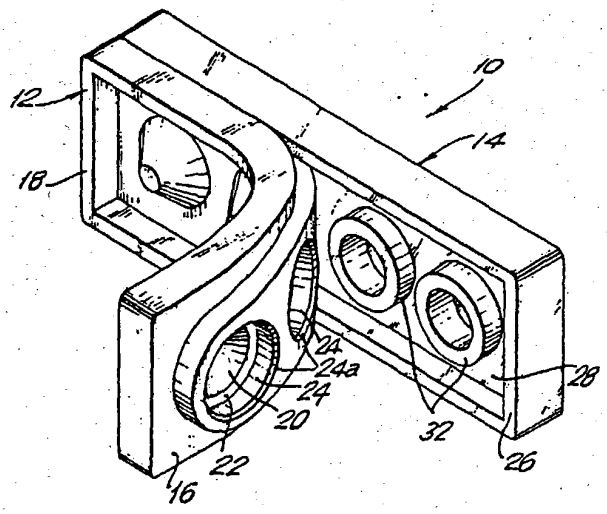
Published
With international search report.

(54) Title: ANALYTICAL CONTAINER



(57) Abstract

A device (10) for conducting chemical and/or biological reactions includes a base member (12) and a cover member (14) joined together and together defining sealed test chambers. One of the members (12) is of flexible material which is releasably and sealingly joined to the other member (14) to provide access to the test chambers. Lens elements (30) are included on one of the members (14) to image the test chambers. The walls of the test chambers may be made of flexible material so that they may be deformed to permit different portions of the test chambers to be imaged by the lens elements (30). A plurality of conically shaped cavities (20) are formed in the base member (12) so that reaction products accumulate in V-shaped lower portions (20a) of the cavities (20) for better visualization.

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ANALYTICAL CONTAINER

BACKGROUND AND BRIEF DESCRIPTION OF THE INVENTION

This invention relates to test devices, and more particularly to a device for conducting a chemical and/or biological reaction. The invention has particular application to biological agglutination reactions.

There is a need for a test device in which a chemical and/or biological reaction may be carried out under the total control of the user, so that reagents or test samples may be introduced into the device and a reaction allowed to proceed to completion, permitting immediate evaluation of the test, preferably by inspection. For example, in immunodiagnostic testing for the presence of an antigen or antibody in a test sample, it would be of great benefit to the physician or technician administering the test if a patient's serum could be easily and simply introduced into a test device for immediate reaction with reagents either already in the device or introduced therein at the time of the test, with the test results being immediately visualized for the purpose of diagnosis. The

present invention provides such a device, and in apresently preferred embodiment constitutes base and cover members that are joined together and which together define a plurality of sealed test chambers wherein reactions may be conducted. Advantageously, one of the members is of flexible material which is releasably and sealingly joined to the other member to provide access to the test chambers for introduction of a patient's serum into those chambers. Lens elements may be included on one of the members for imaging the test chambers. Further, the test chambers may be defined by generally conical cavities which enhance the sensitivity by providing wells for the collection of precipitates that are formed. By making the walls of the test chambers of flexible material, those test chambers may be deformed so that different portions thereof are imaged by the lens elements. Further, variations in focal length of the lens elements may be compensated for by selective deformation of the walls of the test chambers, as necessary.

One of the base and cover members advantageously is of thermoplastic rubber material which is inert to substances used in tests. Preferably that material is colored white, which shows up the various colors of reaction products. That member could be clear for light transmission, as desired, or a color could be selected for good reflection of light, typically provided by white coloration. The thermoplastic rubber has an excellent gripping property, which is utilized for sealing purposes. Because of its flexibility, it may be easily removed to provide access to the test chambers. Those test chambers advantageously may be conically shaped, as noted above, so that a precipitated reaction product tends to collect at

the bottom of the chamber so that it may be readilyvisualized. To aid in visualization lens elements provided in the device image the bottoms of the conical wells and provide magnification, as desired.

Although it is presently preferred to provide a sealed test chamber which is openable, it is of course possible to utilize a permanently sealed test chamber, incorporating a self-sealing element which may be penetrated for the introduction of serum and reagents, as desired, therein.

Although the invention has been described generally above, it will be more completely understood by reference to the following detailed description of a presently preferred embodiment thereof.

IN THE DRAWINGS

Fig. 1 is a perspective view of a test device embodying the present invention in which a flexible base member is shown partially peeled away from an associated cover member to provide access to test chambers.

Fig. 2 is alongitudinal sectional view through a device of the type in Fig. 1.

Fig. 3 is a plan view of a base member forming a part of the device of Figs. 1 and 2.

Fig. 4 is a sectional view of the base member of Fig. 3, taken along the Section 4-4 in Fig. 3.

Fig. 5 is a side view of the base member of Fig. 3.

Fig. 6 is a plan view of a cover member forming a part of the device of Figs. 1 and 2.

Fig. 7 is a longitudinal sectional view of the cover member of Fig. 6, taken along the Section 7-7 in Fig. 6.

DETAILED DESCRIPTION

Referring to Fig. 1, a testing device 10 is shown defined by a base member 12 and a cover member 14. The assembly of Fig. 1 is shown in longitudinal section; in assembled form, in Fig. 2.

Preferably, the base member 12 is of flexible material (it is shown partially "peeled" away from the cover member 10 in Fig. 1) and is of thermoplastic rubber grade, advantageously either pure or oil-modified block copolymer rubbers, such as KRATON thermoplastic rubber grade produced by Shell Chemical Company. Such material is flexible and yet has excellent gripping properties so that it may form an effective seal in the completed device, which may be released as desired for the purpose of adding serum and reagents to test chambers, as will be described below.

Figs. 3 to 5 show the details of the base member 12. It may be of generally white-colored material, so that individual colors of precipitated components may be readily visualized. The base member 12 includes a base section 16 from which a peripheral lip 18 depends from one side thereof around the periphery of the base member. A

plurality of cavities 20 are generally concial in configuration. Although reaction products may tend to accumulate along the sides of the conical cavity, they do tend to concentrate in the V-shaped lower portion 20a of the cavity for better visualization. The cavities 20 terminate at the level of the base section 16 in a ledge 22 bounded by a cylindrical wall 24, which is beveled, as at 24a.

Figs. 6 and 7 show the cover member 14. Preferably, it is formed of transparent rigid plastic material, such as acrylic plastic, formed with a rim 26 extending about the periphery thereof on both sides of an intermediate web section 28. Lens elements 30 depend from one side of the web section 28, while upstanding cylindrical wall members 32 extend from the other side of the base section 28.

The base member 12 and the cover member 14 are interfitted together as shown in Fig. 2. The flexible rubber material of the base member releasably and sealingly engages the cylindrical walls 32 of the cover member, as shown, so that sealed test chambers 34 are provided.

In use, the device is typically positioned on a surface, such as the top of a table, with the orientation as in Fig. 2, so that rim edge 26a is positioned on the table top. The flexible base member 12 is peeled from the cover member 14, as shown in Fig. 1, so that reagents and serum samples, for example, may be inserted into the now-open test chambers 34.

The device is sealed by repositioning the flexible base member 12 to the configuration shown in Fig. 2, and then the device is aggitated and preferably inverted so that it rests on the table top, this time with the edge18 positioned on the table top, with the lens elements 30 being upwardly exposed. Reactions proceed within the test chambers 34, and reaction products that precipitate out are collected in the conical cavities 20. Precipitated reaction products may accumulate along the walls of the cavities, but accumulations will occur in the cavity bottom portions 20a, where they may be easily visualized, particularly with the aid of the lens elements 30.

In this regard, the lens elements 30 are normally fabricated so that they image the lower portions 20a of the conical cavities. Any variations in focal length which may occur because of manufacturing tolerances may be compensated for by flexing the cavity walls 20, by hand. Furthermore, by sufficiently manipulating the flexible cavity walls, any desired portion of a cavity wall may be imaged by the corresponding lens element 30.

As noted above, the complete unit may be sealed, if preferred, so that it is pre-packaged with reagents, if desired, or provision may be made for the insertion of reagents and sample serum into the various test chambers by penetration of the flexible base material 12 by syringe. In this case, the base material 12 should be of self-sealing characteristic, so that the syringe penetration does not result in leakage from the test chambers.

As noted above, the opitcal characteristics of the various parts of the device may vary, depending upon the usage desired. Thus the entire device may be transparent, so that it may be positioned within a spectrophotometer, for example, for optical automated testing. In many cases, however, the device will find applicaiton for visualization of the test results by a physician or a technician, who simply views the cavities through the lens elements following completion of a test procedure.

A device for conducting a chemical and/or biological reaction has been disclosed in its presently preferred form. The embodiment described above is susceptible of modification by those skilled in the art. Accordingly, the invention should be taken to be defined by the following claims.

CLAIMS

1. A device for conducting a chemical and/or biological reaction comprising a housing formed at least in part from a base member and a cover member joined together to define a sealed test chamber wherein said reaction may be conducted, at least one of said members being of flexible material releasably and sealingly joined to the other member to provide access to said test chamber.

2. A device for conducting a chemcial and/or biological reaction comprising a housing defining a sealed test chamber wherein said reaction may be conducted, said housing including a lens element formed therein for imaging a portion of said test chamber.

3. A device for conducting a chemical and/or biological reaction comprising a housing defining a sealed test chamber wherein said reaction may be conducted, said test chamber being fomed at least in part of a cavity which is generally conical in shape so that precipitated reaction products tend to accumulate in said cavity.

4. A device according to any one of claims 1 to 3, in which said test chamber is formed at least in part of self-sealing material permitting reaction material to be introduced into said test chamber by syringe.

5. A device according to any one of claims 1 to 3, in which said test chamber is formed at least in part of transparent material for the passage of light therethrough.

6. A device according to any one of claims 1 to 3, in which said housing defines a plurality of test chambers.

7. A device according to any one of claims 1 or 3, in which said housing includes a lens element formed therein for imaging a portion of said test chamber.

8. A device according to claim 7, in which said housing is formed at least in part of flexible material which may be deformed so that different portions of said test chamber are imaged by said lens element.

9. A device according to claim 2, in which said housing is formed with a cavity which is imaged by said lens element.

10. A device according to claim 9, in which said cavity is generally concial in shape so that precipitated reaction products tend to accumulate in said cavity.

11. A device according to claim 10, in which said housing is formed at least in part of flexible material which may be deformed so that different portions of said cavity are imaged by said lens element.

12. A device according to claim 11, in which said cavity includes a wall structure made of said flexible material.

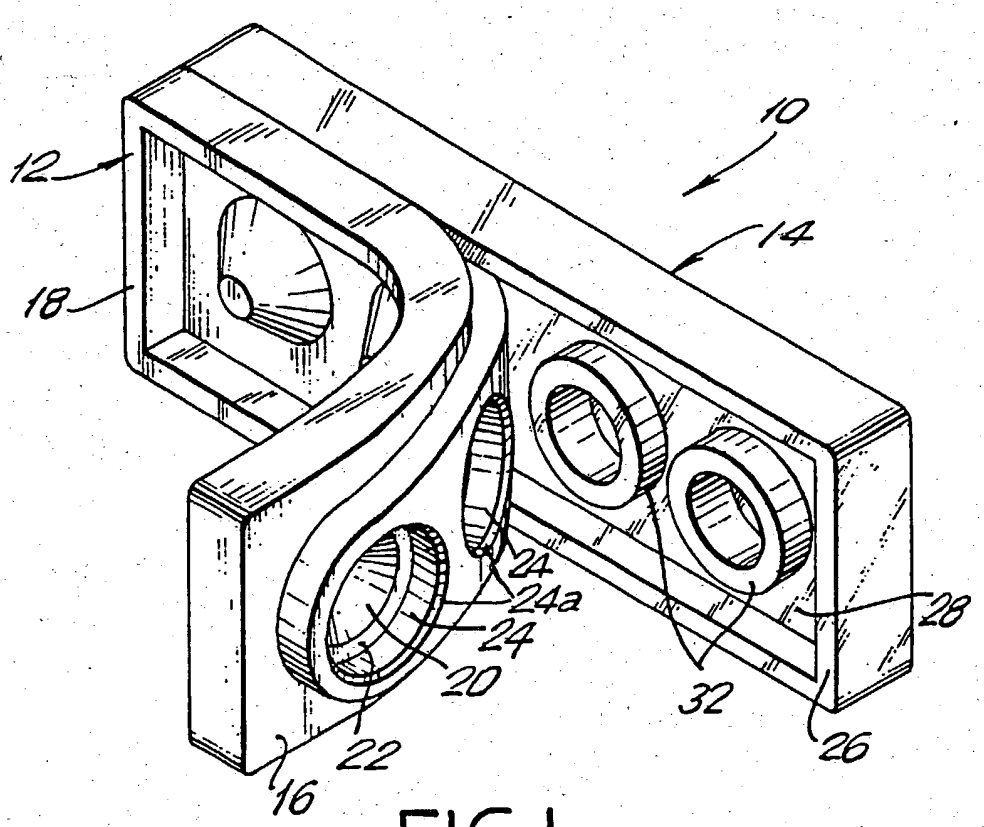
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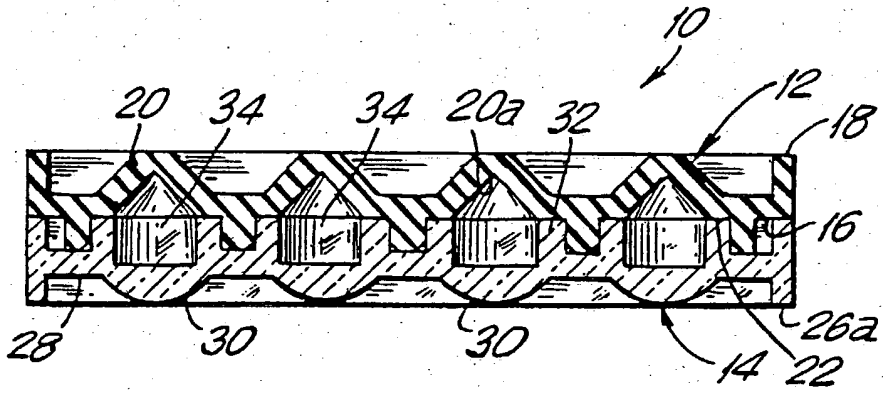
FIG.1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26a

FIG. 2

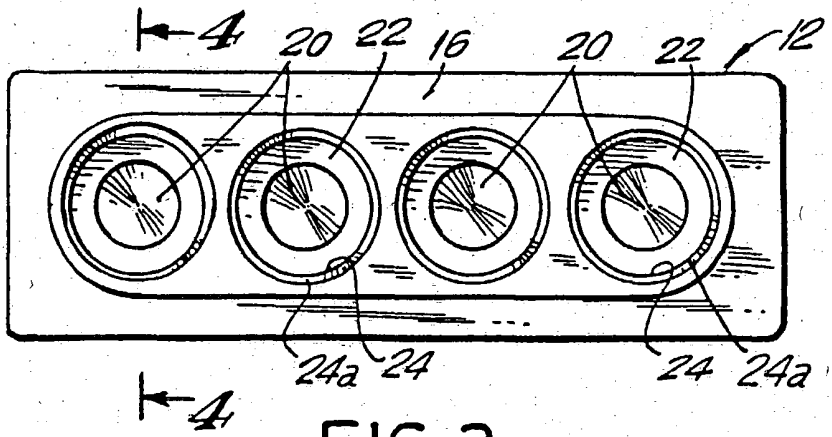

FIG. 3

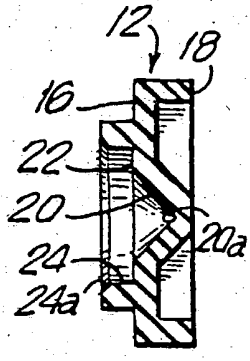

FIG. 4

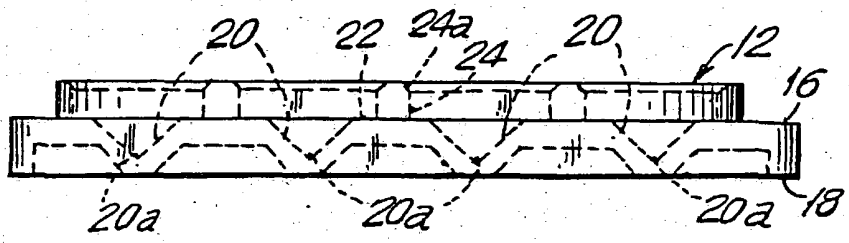

FIG. 5

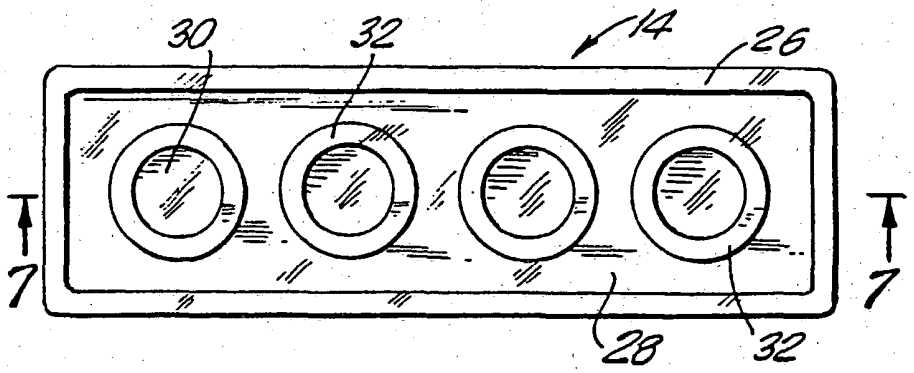

FIG. 6

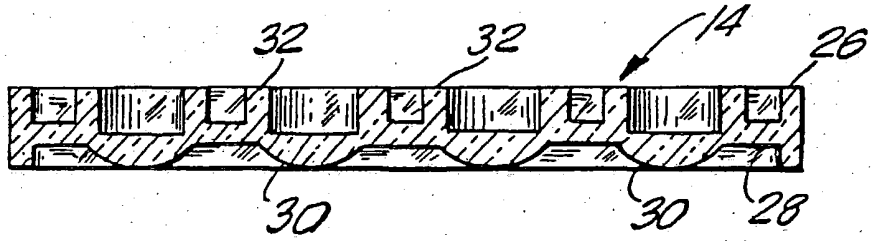

FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No PCT/US86/01241

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(4): B01L 3/00; G01N 21/03

US. CL. 422/58, 102; 356/241, 246; 220/DIG.14

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	356/244, 246; 422/58, 102; 220/DIG.14

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X Y	US, A, 2,606,586 (HILL) 12 AUGUST 1952, SEE COLUMN 2, LINES 12-16 AND 29-35.	1, 5/1 4/1, 6/1, 7/1, 8, 11, 12
X,E Y,E	US, A, 4,599,315 (TERASAKI ET AL) 08 JULY 1986, SEE COLUMN 4, LINES 49-62.	2, 5/2, 6/2,9 4/2, 5/1, 5/3, 7/1, 7/3, 8, 10, 11, 12
X Y	US, A, 3,718,439 (ROSSE ET AL) 02 FEB. 1973, SEE COLUMN 2, LINES 1-10 AND COLUMN 3, LINES 14-45.	2, 5/2, 6/2, 9 4/2, 5/1, 5/3, 7/1, 7/3, 8, 10, 11, 12
X Y	US, A, 4,043,678 (FARRELL ET AL) 23 AUGUST 1977, SEE COLUMN 3, LINES 19-30 AND 56-63 AND COLUMN 4, LINES 7-9.	2, 4/2, 5/2, 6/2, 9 4/1, 4/3, 5/1, 5/3, 7/1, 7/3, 8, 10, 11, 12
Y	US, A, 4,465,938 (KATO ET AL) 14 AUGUST 1984, SEE COLUMN 2, LINES 36-37 AND COLUMN 3, LINES 62-67.	3, 4/3, 5/1, 5/2, 5/3, 6/1, 6/2, 6/3, 7/3, 8, 10, 11, 12

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
19 August 1986	29 AUG 1986
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	C.M. Delahunty C.M. Delahunty

Form PCT/ISA/210 (second sheet) (May 1986)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . ... .. because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

I. Claims 1, 4/1, 5/1, 6/1, 7/1, and 8
II. Claims 2, 4/2, 5/2, 6/2, and 9-12
III. Claims 3, 4/3, 5/3, 6/3, and 8

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application. Telephone Practice

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No [18]
Y	US, A, 4,251,159 (WHITE) 17 FEB. 1981, SEE COLUMN 2, LINES 22-26 AND COLUMN 3, LINES 17-30 AND COLUMN 4, LINES 12-13.	1, 4/1, 4/2, 4/3, 5/1, 5/2, 5/3, 6/1, 6/2, 6/3, 7/1, 8, 11, 12
Y	US, A, 4,431,307 (SUIVANIEMI) 14 FEB. 1984, SEE COLUMN 1, LINES 45-50.	2, 2/4, 5/1, 5/2, 5/3, 6/1, 6/2, 6/3, 7/1, 7/3, 9, 11
Y	US, A, 4,391,780 (BORIS) 05 JULY 1983 SEE COLUMN 2, LINES 30-37.	4/1, 4/2, 4/3, 6/1, 6/2, 6/3
Y	GB A, 1,196,374 (WATSON-MALOW INSTRUMENTS, LIMITED) 24 JUNE 1970 SEE PAGE 1, LINES 41-80 AND PAGE 2, LINES 1-10	1, 5/1, 5/2, 5/3, 6/1, 6/2, 6/3, 8, 11, 12

Attachment To Form PCT/ISA/210, Part VI. 1.

Telephone approval:

$280 payment approved by Bradford F. Breen (Reg.# 30823) on 18 August 1986 for Groups II and III; charge to Deposit Account No. 30823.

Reasons for holding lack of Unity of invention:

The invention of Group I could be used as a storage vessel lacking a lens and/or a conical wall, the invention of Group II could be used as a cuvette lacking a flexible wall and/or a conical wall and the invention of Group III could be used as an agglutination vessel lacking a flexible wall and/or a lens.